

Application No. 10/635,483  
Amendment dated December 23, 2005  
Reply to Examiner's Report of June 28, 2005

### REMARKS/ARGUMENTS

By the present amendment, claims 1, 3, 4, 8 - 10, 12, 14, have been amended, claims 11 and 13 have been canceled, claims 2, 5 - 7, 15 - 18 are original and new claims 19 - 23 have been added.

In the Office action under reply, claims 1 - 17 were rejected under 35 U.S.C. 102(b) as being anticipated by Woo (U.S. Patent No. 6,012,920).

In discussing this alleged anticipation, Applicant wishes firstly to explain the different uses of the present invention and that of the Woo reference.

The present invention is particularly useful as a diagnostic and bite registration device, rather than as a treatment appliance.

More particularly, the present device is intended for attended polysomnographic sleep studies, during which the device is adjusted by an attending sleep technologist, while a patient equipped with the present device is asleep. This enables the technologist to record the setting most likely to be advantageous in the subsequent treatment procedures with whatever device may be selected for that purpose, e.g. the device taught by the Woo reference.

The present invention is also of use in determining, in advance of subsequent fabrication of a sleep disorder treatment device, the positive effect or the lack thereof of mandibular manipulation in expanding the patient's airway.

Application No. 10/635,483  
Amendment dated December 23, 2005  
Reply to Examiner's Report of June 28, 2005

The present device has adjustment members, e.g. the adjustment screws 34, 50 and 58 shown in the drawings, which are provided on projections extending from the bite blocks past the patient's lips

to the exterior of the patient's mouth and which, therefore, can be adjusted at the exterior of the patient's mouth, by the sleep technologist rather than by the patient, while the patient is asleep.

The information obtained with the present device, in the manner described above, can be critical in the selection of appropriate treatment. Thus, there is no point in fabricating an oral appliance for the treatment of sleep disorders if the mandibular manipulations which can be registered by the use of the present invention are ineffective in reducing obstructive events during the course of the sleep study.

The device taught by the cited reference is not intended to be used as a diagnostic device and consequently is not intended to be adjusted while a patient is asleep. In fact, the Woo device cannot be adjusted when being used by a patient who is asleep, but must be adjusted by the patient or someone else while the patient is awake.

These differences in the functions of the present invention and the Woo device are reflected in the differences between the components of these devices, as discussed below.

The Woo device is adjustable by rotation of a collar 60 to increase or decrease the distance between the screws 40, 50 to fix the mandibular tray in a selected position relative to the mandibular tray 4 in the posterior/anterior directions (see col 5, lines 56 -63).

Also, vertical hinges (i.e the connections between the pins 20 and the adjusting screws (40, 50) allow vertical movement. However, there is no adjustment screw for effecting this vertical movement.

Application No. 10/635,483  
Amendment dated December 23, 2005  
Reply to Examiner's Report of June 28, 2005

The present invention provides a pair of adjustment members, e.g. screws, for respectively adjusting both the relative vertical displacements and also the relative horizontal displacements of the bite blocks, so that these displacements can be adjusted progressively and finely.

A further distinction over the Woo reference is that in the present invention the adjustable connection between the upper and lower bite trays is provided at projections extending forwardly from the bite trays. In the drawings, these projections are indicated by reference numerals 24 and 26.

This has the advantage that the present device is adjustable at the exterior of the patient's mouth, e.g. while the patient is asleep, as discussed above, in contrast to the Woo device, which requires access to the interior of the patient's mouth to remove, adjust and replace the device.

It is particularly noted that the Woo device has been cited under 35 U.S.C. 102(b) as anticipating the originally filed claims of this application. The Examiner has summarized the disclosure of the Woo reference but has not indicated which features of these claims he considers to be anticipated by the features disclosed in the Woo reference.

Referring now to the claims presently in this application, claim 1 recites:-

“a manually adjustable screw for displacing said lower bite block relative to said upper bite block”.

In the Woo reference, the vertical displacement is effected not by an adjustment screw but by moving the mandibular and maxillary trays relative to one another and the vertical hinges, between the pins 20 and the adjustment screw 40, 50, merely allow such vertical displacement. Therefore, the above feature recited in claim 1 is not anticipated by the Woo reference.

Application No. 10/635,483  
Amendment dated December 23, 2005  
Reply to Examiner's Report of June 28, 2005

Claim 1 also recites:-

"said adjustable connection protruding forwardly from said upper and lower bite blocks so that, in use of said mandible positioning device, said manually adjustable connection is located in front of a patient fitted with said mandible".

In contrast, Woo discloses a device which does not protrude forwardly from the trays 2 and 4 and which therefore also lacks this feature recited in claim 1.

Claims 2 through 5, depend from claim 1 and claim 1 is therefore not anticipated by this reference and, are therefore likewise not anticipated by the Woo reference and, in addition, recite further features not anticipated by Woo.

Claim 6 recites:-

"said adjustable connection comprising a first adjustment screw having a longitudinal axis parallel to said plane, and a second adjustment screw having a longitudinal axis perpendicular to said plane".

Woo does not disclose two adjustment screws having longitudinal axes parallel to and perpendicular to a plane and therefore does not anticipate the features recited in claim 6.

Claim 7 depends from claim 6 and is therefore likewise distinguished from the disclosure of the Woo reference, and in addition the features recited in claim 7 are not anticipated by Woo.

Application No. 10/635,483  
Amendment dated December 23, 2005  
Reply to Examiner's Report of June 28, 2005

Claim 8 recites:-

"said manually adjustable connection including manually adjustable screws for effecting relative displacement of said mandibular and maxillary dentition engagement components parallel and perpendicular to said plane".

No such screws are disclosed in the Woo reference, which therefore fails to anticipate the features recited in claim 8.

Claim 9 depends from claim 8 and is therefore likewise not anticipated by Woo and in addition recites further features which do not appear in the Woo reference.

Claim 10 has been amended to recite that:-

"said adjustable connection includes first and second adjustment members which are manually adjustable independently of one another for effecting the relative vertical and horizontal adjustment, respectively, of said mandibular and maxillary dentition engagement components".

Woo does not disclose first and second adjustment members which are manually adjustable independently of one another for effecting such relative vertical and horizontal adjustment, and therefore clearly does not anticipate this claim.

Claim 12 depends from claim 10 and is therefore likewise not anticipated by Woo, in addition to reciting further features which are also not anticipated by Woo.

Application No. 10/635,483  
Amendment dated December 23, 2005  
Reply to Examiner's Report of June 28, 2005

Claim 14 recites:-

"said adjustable connection protruding forwardly of said mandibular and maxillary dentition engagement components so as to accessible at the exterior of a patient's mouth when said pharyngeal airway adjuster is in use".

As discussed above, Woo does not disclose this feature and therefore fails to anticipate claim 14.

Claim 15 recites an adjustable connection comprising:-

"comprising a first adjustment screw which is rotatably adjustable to effect relative displacement of said upper and lower bite blocks forwardly and rearwardly relative to one another and a second adjustment screw which is rotatably adjustable to effect relative adjustment of said upper and lower bite blocks towards and away from one another".

Since Woo does not disclose the use of two adjustment screws for these two types of relative movement, Woo does not anticipate this claim.

Claims 14 through 18 depend from claim 15 and therefore are likewise not anticipated by Woo, in addition to reciting additional features which are also not anticipated by Woo.

Claim 19 recites:-

"an adjustable connection between said upper and lower projections, said adjustable connection comprising a first adjustment member which is manually adjustable to displace

Application No. 10/635,483  
Amendment dated December 23, 2005  
Reply to Examiner's Report of June 28, 2005

said upper and lower bite blocks vertically relative to one another and a second adjustment member which is manually adjustable to displace said upper and lower bite blocks horizontally relative to one another;

said adjustable connection being located forwardly from the upper and lower bite blocks so as to protrude beyond the mouth and lips of the patient".

Neither of these features of claim 19 is disclosed by the Woo reference, which therefore does not anticipate this claim.

Claim 20 through 22 are dependent from claim 19 and are therefore likewise not anticipated by Woo, in addition to reciting that the adjustment members comprise adjustment screws, which further distinguishes these claims from the Woo reference. Claim 22 further recites a third adjustment screw which is also not anticipated by Woo.

Claim 23 recites:-

"an adjustable connection between said upper and lower bite blocks, said adjustable connection comprising a first adjustment screw which is rotatable to displace said upper and lower bite blocks vertically relative to one another and a second adjustment screw which is rotatable to displace said upper and lower bite blocks horizontally relative to one another; said adjustable connection being between the upper and lower projections of said upper and lower bite blocks".

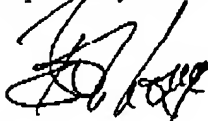
Woo does not disclose such adjustment screws nor the provision of an adjustable connection between upper and lower bite block projections, and therefore does not anticipate this claim.

Application No. 10/635,483  
Amendment dated December 23, 2005  
Reply to Examiner's Report of June 28, 2005

It is accordingly respectfully submitted that none of the claims presently in this application is anticipated by the Woo reference and that the application is therefore now in order for allowance.

Allowance of the application is accordingly respectfully requested.

Respectfully submitted,



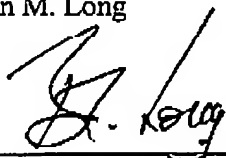
Brian M. Long  
Reg. No. 28,815  
LONG AND CAMERON  
1401 - 1166 Alberni Street  
Vancouver, B.C.  
Canada V6E 3Z3  
Tel: (604) 687-5513  
Fax: (604) 687-5756

J1508.317

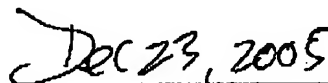
#### Certification of Facsimile Transmission

I hereby certify that this paper is being facsimile transmitted to the Patent and Trademark Office on the date shown on the first page of this document.

Brian M. Long



Signature



Date